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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,715	01/22/2004	Kristian DiMatteo	706182-2001	5203

7590 04/07/2011  
Bingham McCutchen LLP  
2020 K Street, NW  
Washington, DC 20006

EXAMINER
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GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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04/07/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/762,715	<b>Applicant(s)</b> DIMATTEO ET AL.	
	<b>Examiner</b> Phillip Gray	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-19,21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-19,21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This office action is in response to applicant's communication of 1/25/2011. Currently claims 1-5, 7-19, 21, and 23-24 are pending and stand rejected below. This rejection is a Final Rejection.

### ***Response to Arguments***

Applicant's arguments filed 1/25/2011 have been fully considered but they are not persuasive (with respect to claims 1-5, 7-19, 21, and 23-24). Applicant's argue that the prior art reference of Dryden fails to suggest a "pressure relief valve" or "overpressure control element". Further applicants argue that Armenia fails to teach an overpressure control element. Examiner is of the position that Dryden does teach a "pressure relief valve" or "overpressure control element" and in the alternative if the valves of Dryden are found to not be "pressure relief valves" or overpressure control elements" then it would have been an obvious modification to construct them as "pressure relief valves" and "overpressure control elements". Further it is examiners position that Armenia does disclose an "overpressure control element".

Concerning Dryden, the over pressure control element (35 or 36) would be fully capable of being adapted to maintain a pressure of fluid within the connector below a predetermined threshold (as described in column 2 lines 45-56) and be a pressure relief valve.

"The amount of vacuum applied can be controlled by the valve 36. This can be a conventional roller valve of the type used on

intravenous feeding tubes. Other valve types might be used. Another example is the squeeze-to-open, automatic-closure, type. Similarly, the amount of irrigation fluid supplied can be controlled by valve 35.”

It is examiners position that these valves since they regulate the amount of gas or liquid through the system would be a type of “overpressure control element”. By controlling the amount and regulating (also the teaching that it could be other valves like squeeze to open, automatic-closure, ect), these valves would be a type of pressure relief valves.

Although it is examiners position that Dryden discloses overpressure control element or “pressure relief valve” adapted to maintain a flow and pressure of fluid within the connector below a predetermined threshold (valve 35/36 i.e. and its function); but in the alternative it would have been an obvious modification thereof and well known to a person having ordinary skill in the art to construct the valve (35) to be an “over pressure control element” to allow a safe pressure level of fluid to reach a patient, and be a pressure relief valve. Such valves are well known in the art. It is examiners position that when one regulates fluid or a gas through a system, the pressure should be maintained within an acceptable range. In order to regulate it at the upper range a pressure relief valve is one component known to be used by a person having ordinary skill in the art at the time of the invention.

Concerning the arguments in reference to the Armenia prior art, it is examiners position that Armenia teaches that it is known to use an overpressure control element

being an extension tube and having a external collection jacket (Armenia 30) disposed around as set forth in paragraphs at columns 3-4 to provide a controlling means to contain a spill or rupture within the device. This spill or rupture would occur when the pressure in the interior tube was to great and the interior tube ruptured releasing the fluid and pressure within the outer tube. This would be a overpressure control element and further a pressure relief type structure system. See rejection below.

Examiner has fully considered applicant's arguments but they are not compelling. It is examiners position that given a careful reading, the claims as written, they do not distinguish themselves over the prior art of record. The examiner has the position that the rejections are proper because all structures are taught and are fully capable of performing all claimed functional, spatial, and operational limitations (see previous office action rejections). Therefore the standing rejections are proper and maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-19, 21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden (U.S. Patent 5,125,893) in view of Armenia et al. (U.S. Patent 6,446,671).

Dryden discloses a catheter system with a connector for injecting fluid to a catheter (as in figure 1) comprising an attachment portion (near 27) to fluidly couple to a source of pressurized fluid (12 for example), an elongate tubular hypotube bypass element (element 31/28) adapted to open a valve (such as 23) of the catheter (such as system 11/17/22) to permit fluid to flow into the catheter without impinging on the valve (as described in columns 2-3, wherein the tubular bypass element has a diameter to fit in a flow opening of the valve) and an over pressure control element (35 or 36) which would be fully capable of being adapted to maintain a pressure of fluid within the

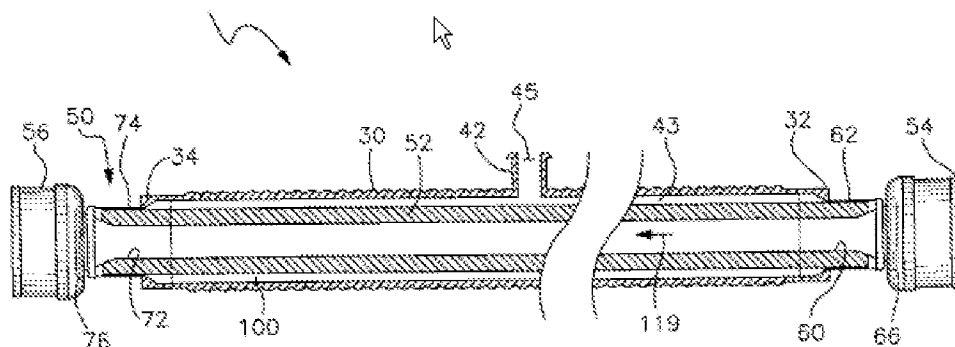
connector below a predetermined threshold (as described in column 2 lines 45-56) and be a pressure relief valve. It is examiners position that an overpressure control element or “pressure relief valve” (as identified in applicant’s claim 7) adapted to maintain a pressure of fluid within the connector below a predetermined threshold level is inherent in the Dryden reference (valve 35 i.e. and its function) but in the alternative it would have been an obvious modification thereof and well known to a person having ordinary skill in the art to construct the valve (35) to be an “over pressure control element” to allow a safe pressure level of fluid to reach a patient, and be a pressure relief valve. Such valves are well known in the art.

It is examiners position that the bypass element is fully capable of being adapted to open a pressure actuated safety valve of a venous catheter, and that the attachment portion is fully capable of being adapted to connect to a contrast media power injection system. It has been held that the recitation that an element is “adapted to” to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. The elements disclosed in Dryden are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper.

Dryden discloses the claimed invention except for the overpressure control element being an extension tube and having a external collection jacket disposed around with a space between. Armenia teaches that it is known to use an overpressure control element being an extension tube and having a external collection jacket

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(Armenia 30) disposed around as set forth in paragraphs at columns 3-4 to provide a controlling means to contain a spill or rupture within the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Dryden with an overpressure control element being an extension tube and having a external collection jacket disposed around as taught by Armenia, since such a modification would provide the system with the overpressure control element extension tube and an external collection jacket for providing a controlling means to contain a spill or rupture within the device.



Dryden in view of Armenia discloses the claimed invention except for the threshold level being approximately 300, 100, 80, or 40 p.s.i.. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the threshold level to be approximately 300, 100, 80, or 40 p.s.i., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ



233 (CCPA 1955), and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to u whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gray/  
Examiner, Art Unit 3767

/Theodore J Stigell/  
Primary Examiner, Art Unit 3763